

This document is scheduled to be published in the Federal Register on 07/26/2012 and available online at http://federalregister.gov/a/2012-17987, and on FDsys.gov

Billing Code: 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-12-0666]

Proposed Data Collections Submitted for
Public Comment and Recommendations

In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Centers for Disease Control and Prevention (CDC) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call 404-639-7570 and send comments to Kimberly S. Lane, CDC Reports Clearance Officer, 1600 Clifton MS-D74, Atlanta, GA Road, 30333 or send an email omb@cdc.gov.

invited (a) Whether are on: the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d)

ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Written comments should be received within 60 days of this notice.

Proposed Project

National Healthcare Safety Network (NHSN) (OMB No. 0920-0666), exp. 01/31/2015 - Revision - National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The National Healthcare Safety Network (NHSN) is a system designed to accumulate, exchange, and integrate relevant information and resources among private and public stakeholders to support local and national efforts to protect patients and promote healthcare safety. Specifically, the data is used to determine the magnitude of various healthcare-associated adverse events and trends in the rates of these events among patients and healthcare workers with similar risks. The data will be used to detect changes in the epidemiology of adverse events resulting from new and current medical therapies and changing risks. The NHSN consists of four components: Patient Safety, Healthcare Personnel Safety, Biovigilance, and Long-Term Care Facility (LTCF). In general, the data reported under the Patient

Safety Component protocols are used to (1) determine the magnitude of the healthcare-associated adverse events under study, trends in the rates of events, in the distribution of pathogens, and in the adherence to prevention practices, and (2) changes in the epidemiology of adverse resulting from new medical therapies and changing patient risks. Additionally, reported data will be used to describe the epidemiology of antimicrobial use and resistance understand the relationship of antimicrobial therapy to this growing problem. Under the Healthcare Personnel Safety Component protocols, data on events, both positive and adverse, are used to determine (1) the magnitude of adverse events in healthcare personnel and (2) compliance with immunization and injuries safety guidelines. Under the Biovigilance Component, data on adverse reactions and incidents associated with blood transfusions are used to provide national estimates of adverse reactions and incidents. The Long-Term Care Facility (LTCF) Component is used to more specifically and appropriately capture the residents of skilled nursing facilities. Surveillance methods and definitions for this component specifically address the nuances of LTCF residents.

This revision submission includes major revisions to the Patient Safety Component - Outpatient Dialysis Center Practices Survey (Form 57.104) in an effort to provide further

clarification to those collecting the information. Additionally, some of the changes have been made to improve surveillance data available for the outpatient dialysis population. Due to the CMS End Stage Renal Disease (ESRD) Quality Improvement Program (QIP) reporting requirements, over 5,700 dialysis facilities have already enrolled or will enroll into NHSN to report data in 2012. Form 57.104 is completed by each facility upon enrollment into NHSN and then every January thereafter.

Furthermore, minor revisions have been made to 28 other forms within the package to clarify and/or update surveillance definitions. Six forms have been removed for the purposes of simplification from the Healthcare Personnel Safety Component of the package due to changes within NHSN reporting of healthcare personnel influenza vaccination. Old functionality of individual level vaccination reporting will be removed from NHSN. CMS Inpatient Quality Reporting (IQR) requirements designate that all acute care facilities will report healthcare personnel vaccination counts at the summary level for the 2012-2013 flu season.

The previously approved NSHN package included 54 individual collection forms; the current revision request removes six forms for a total of 48 forms. The reporting burden will decrease by 415,523 hours, for a total of 3,562,653 hours.

Healthcare institutions that participate in NHSN report their data to CDC using a web browser based technology for data entry and data management. Data are collected by trained surveillance personnel using written standardized protocols. Participating institutions must have a computer capable of supporting an Internet service provider (ISP) and access to an ISP. There is no cost to respondents other than their time.

Estimate of Annualized Burden Hours

			No. of Responses	Avg. Burden per response	Total burden
Form number and name	Type of Respondents	Number of respondents	per respondent	(in hours)	(in hours)
Total name and name	Registered Nurse	_ coponacios	respondent	110 02 57	11001157
57.100: NHSN	(Infection				
Registration Form	Preventionist)	2,000	1	5/60	167
	Registered Nurse			·	
57.101: Facility	(Infection				
Contact Information	Preventionist)	2,000	1	10/60	333
57.103: Patient Safety	Registered Nurse				
ComponentAnnual	(Infection				
Hospital Survey	Preventionist)	6,000	1	30/60	3,000
57.104: Patient Safety					
ComponentOutpatient	Registered Nurse				
Dialysis Center	(Infection				
Practices Survey	Preventionist)	5,700	1	1.5	8,550
	Registered Nurse				
57.105: Group Contact	(Infection		_	- /	
Information	Preventionist)	6,000	1	5/60	500
55 106 D. I. I. G. S. I.	Registered Nurse				
57.106: Patient Safety	(Infection	10.000	10	25/60	70.000
Monthly Reporting Plan	Preventionist)	10,000	12	35/60	70,000
57.108: Primary Bloodstream Infection	Registered Nurse (Infection				
(BSI)	Preventionist)	6,000	36	35/60	126,000
57.109: Dialysis Event	Staff RN	5,700	60	16/60	91,200
Ji. 109: Dialysis Event	Registered Nurse	3,700	00	10/00	91,200
57.111: Pneumonia	(Infection				
(PNEU)	Preventionist)	6,000	72	32/60	230,400
57.112: Ventilator-	Registered Nurse	0,000	, 2	32,00	230,100
Associated Event	(Infection				
	Preventionist)	6,000	144	25/60	360,000

Infection (UTI)	57.114: Urinary Tract	Infection				1
			6 000	27	32/60	86 400
For Neonatal Intensive Care Unit (NICU)		Flevencionisc	0,000	27	32/00	00,400
Care Unit (NICU)						
S7.117: Denominators for Specialty Care Area (SCA) / Oncology (ONC)		Ctaff DN	6 000	۵	2	162 000
For Specialty Care Area (SCA)/Oncology (ONC) Staff RN 6,000 9 5 270,000		Stall KN	0,000	9	3	102,000
Area (SCA)/Oncology (ONC)						
CONC Staff RN 6,000 9 5 270,000 57.118: Denominators for Intensive Care Unit (ICU)/Other 10cations (not NICU or SCA) Staff RN 6,000 18 5 540,000 57.119: Denominator for Outpatient Dialysis Staff RN 5,700 12 6/60 6,840						
S7.118: Denominators for Intensive Care		at-ff DN	6 000	0	_	070 000
For Intensive Care	` '	Stall RN	6,000	9	5	270,000
Unit (ICU)/Other locations (not NICU or SCA)						
locations (not NICU or SCA)						
SCA Staff RN 6,000	•					
57.119: Denominator for Outpatient Dialysis					_	
Staff RN 5,700 12 6/60 6,840		Staff RN	6,000	18	5	540,000
Dialysis						
S7.120: Surgical Site						
S7.120: Surgical Site	Dialysis		5,700	12	6/60	6,840
Infection (SSI)						
S7.121: Denominator						
Staff RN	Infection (SSI)	Preventionist)	6,000	36	32/60	115,200
S7.123: Antimicrobial Use and Resistance (AUR)-Microbiology Data Electronic Upload Specification Tables Technician 6,000 12 5/60 6,000	57.121: Denominator					
Use and Resistance (AUR) -Microbiology Data Electronic Upload Specification Tables Technician 57.124: Antimicrobial Use and Resistance (AUR) -Pharmacy Data Electronic Upload Specification Tables Technician Flectronic Upload Specification Tables Technician Technic	for Procedure	Staff RN	6,000	540	5/60	270,000
(AUR) -Microbiology Data Electronic Upload Specification Tables Technician 6,000 12 5/60 6,000 57.124: Antimicrobial Use and Resistance (AUR) -Pharmacy Data Electronic Upload Specification Tables Technician 6,000 12 5/60 6,000 57.125: Central Line Insertion Practices Adherence Monitoring Preventionist) 1,000 100 5/60 8,333 Registered Nurse (Infection Infection Form Preventionist) 6,000 72 32/60 230,400 57.127: MDRO and CDI Prevention Process and Outcome Measures Monthly Monitoring Preventionist) 6,000 24 10/60 24,000 57.128: Laboratory- Registered Nurse	57.123: Antimicrobial					
Data Electronic Upload Specification Tables Technician 6,000 12 5/60 6,000 57.124: Antimicrobial Use and Resistance (AUR) - Pharmacy Data Electronic Upload Pharmacy Specification Tables Technician 6,000 12 5/60 6,000 57.125: Central Line Registered Nurse Insertion Practices (Infection Adherence Monitoring Preventionist) 1,000 100 5/60 8,333 Registered Nurse (57.126: MDRO or CDI (Infection Infection Form Preventionist) 6,000 72 32/60 230,400 57.127: MDRO and CDI Prevention Process and Outcome Measures (Infection Monthly Monitoring Preventionist) 6,000 24 10/60 24,000 57.128: Laboratory- Registered Nurse	Use and Resistance					
Data Electronic Upload Specification Tables Technician 6,000 12 5/60 6,000 57.124: Antimicrobial Use and Resistance (AUR) - Pharmacy Data Electronic Upload Pharmacy Specification Tables Technician 6,000 12 5/60 6,000 57.125: Central Line Registered Nurse Insertion Practices (Infection Adherence Monitoring Preventionist) 1,000 100 5/60 8,333 Registered Nurse (57.126: MDRO or CDI (Infection Infection Form Preventionist) 6,000 72 32/60 230,400 57.127: MDRO and CDI Prevention Process and Outcome Measures (Infection Monthly Monitoring Preventionist) 6,000 24 10/60 24,000 57.128: Laboratory- Registered Nurse	(AUR)-Microbiology					
Specification Tables Technician 6,000 12 5/60 6,000 57.124: Antimicrobial Use and Resistance (AUR)-Pharmacy Data Electronic Upload Pharmacy Specification Tables Technician 6,000 12 5/60 6,000 57.125: Central Line Registered Nurse Insertion Practices (Infection Adherence Monitoring Preventionist) 1,000 100 5/60 8,333 Registered Nurse (Infection Practices (Infection Preventionist) 6,000 72 32/60 230,400 57.126: MDRO or CDI (Infection Prevention		Laboratory				
57.124: Antimicrobial Use and Resistance (AUR)-Pharmacy Data Electronic Upload Specification Tables Technician Form Insertion Practices Adherence Monitoring Freventionist Infection Form Infection Form Frevention Process and Outcome Measures Monthly Monitoring Monthly Monitoring Frevention Preventionist Form Monthly Monitoring Freventionist Form Freventi			6,000	12	5/60	6,000
(AUR) - Pharmacy Data Electronic Upload Specification Tables Technician Formula Registered Nurse Insertion Practices Adherence Monitoring Formula Preventionist) Technician Formula Registered Nurse Insertion Practices Adherence Monitoring Freventionist) Topic Infection Infection Formula Preventionist) Formula Registered Nurse Formula Registered Nurse Infection Formula Registered Nurse Infection Process and Outcome Measures Infection Monthly Monitoring Freventionist) Formula Registered Nurse Formula Registered Nurse Infection Formula Registered Nurse Formula Register	-		,		,	
(AUR) - Pharmacy Data Electronic Upload Specification Tables Technician Formula Registered Nurse Insertion Practices Adherence Monitoring Formula Preventionist) Technician Formula Registered Nurse Insertion Practices Adherence Monitoring Freventionist) Topic Infection Infection Formula Preventionist) Formula Registered Nurse Formula Registered Nurse Infection Formula Registered Nurse Infection Process and Outcome Measures Infection Monthly Monitoring Freventionist) Formula Registered Nurse Formula Registered Nurse Infection Formula Registered Nurse Formula Register	Use and Resistance					
Electronic Upload Pharmacy Specification Tables Technician 6,000 12 5/60 6,000 57.125: Central Line Registered Nurse Insertion Practices (Infection Adherence Monitoring Preventionist) 1,000 100 5/60 8,333 Registered Nurse (Infection Infection Form Preventionist) 6,000 72 32/60 230,400 57.127: MDRO and CDI Prevention Process and Outcome Measures (Infection Monthly Monitoring Preventionist) 6,000 24 10/60 24,000 57.128: Laboratory- Registered Nurse						
Specification Tables Technician 6,000 12 5/60 6,000 57.125: Central Line Registered Nurse (Infection Adherence Monitoring Preventionist) 1,000 100 5/60 8,333 Registered Nurse (Infection Infection Form Preventionist) 6,000 72 32/60 230,400 57.127: MDRO and CDI Prevention Process and Outcome Measures (Infection Monthly Monitoring Preventionist) 6,000 24 10/60 24,000 57.128: Laboratory- Registered Nurse	_	Pharmacy				
57.125: Central Line Registered Nurse (Infection Adherence Monitoring Preventionist) 1,000 100 5/60 8,333 Registered Nurse (Infection Preventionist) 6,000 72 32/60 230,400 57.126: MDRO or CDI (Infection Preventionist) 6,000 72 32/60 230,400 57.127: MDRO and CDI Prevention Process and Outcome Measures (Infection Monthly Monitoring Preventionist) 6,000 24 10/60 24,000 57.128: Laboratory- Registered Nurse	_	-	6,000	12	5/60	6.000
Insertion Practices (Infection Adherence Monitoring Preventionist) 1,000 100 5/60 8,333 Registered Nurse (Infection Infection Form Preventionist) 6,000 72 32/60 230,400 57.127: MDRO and CDI Prevention Process and Outcome Measures (Infection Monthly Monitoring Preventionist) 6,000 24 10/60 24,000 57.128: Laboratory- Registered Nurse	_		.,			,,,,,,
Adherence Monitoring Preventionist) 1,000 100 5/60 8,333 Registered Nurse (Infection Preventionist) 6,000 72 32/60 230,400 57.127: MDRO and CDI Prevention Process and Outcome Measures (Infection Preventionist) 6,000 24 10/60 24,000 57.128: Laboratory- Registered Nurse						
Registered Nurse (Infection Infection Form Preventionist) 57.127: MDRO and CDI Prevention Process and Outcome Measures Monthly Monitoring Preventionist) Registered Nurse (Infection Monthly Monitoring Preventionist) 6,000 24 10/60 24,000 57.128: Laboratory- Registered Nurse			1 000	100	5/60	8 333
57.126: MDRO or CDI (Infection Preventionist) 6,000 72 32/60 230,400 57.127: MDRO and CDI Prevention Process and Outcome Measures (Infection Monthly Monitoring Preventionist) 6,000 24 10/60 24,000 57.128: Laboratory- Registered Nurse	Hanerence Homreoring		1,000	100	3700	0,333
Infection Form Preventionist) 6,000 72 32/60 230,400 57.127: MDRO and CDI Prevention Process and Outcome Measures (Infection Monthly Monitoring Preventionist) 6,000 24 10/60 24,000 57.128: Laboratory- Registered Nurse	57 126, MDPO or CDI					
57.127: MDRO and CDI Prevention Process and Registered Nurse Outcome Measures (Infection Monthly Monitoring Preventionist) 6,000 24 10/60 24,000 57.128: Laboratory- Registered Nurse			6 000	72	32/60	230 400
Prevention Process and Registered Nurse Outcome Measures (Infection Monthly Monitoring Preventionist) 6,000 24 10/60 24,000 57.128: Laboratory- Registered Nurse		Fievencionisc)	0,000	72	32/00	230,400
Outcome Measures (Infection Preventionist) 6,000 24 10/60 24,000 57.128: Laboratory- Registered Nurse		Pogistored Nurse				
Monthly Monitoring Preventionist) 6,000 24 10/60 24,000 57.128: Laboratory- Registered Nurse						
57.128: Laboratory- Registered Nurse			6 000	2.4	10/60	24 000
			6,000	24	10/60	24,000
identified MDDO on CDI /Infortion	_					
identified MDRO or CDI (Infection			6 000	242	15/60	260 000
Event Preventionist) 6,000 240 15/60 360,000			6,000	∠40	15/60	360,000
57.130: Vaccination Registered Nurse						
Monthly Monitoring (Infection			6 000	_		400 000
Form-Summary Method Preventionist) 6,000 5 14 420,000	-	Preventionist)	6,000	5	14	420,000
57.131: Vaccination						
Monthly Monitoring Registered Nurse						
Form-Patient-Level (Infection						
Method Preventionist) 2,000 5 2 20,000	Method		2,000	5	2	20,000
Registered Nurse						
57.133: Patient (Infection						
Vaccination Preventionist 2,000 250 10/60 83,333	Vaccination	•	2,000	250	· · · · · · · · · · · · · · · · · · ·	83,333
57.137: Long-Term Care Registered Nurse 250 1 45/60 188	57.137: Long-Term Care	Registered Nurse	250	1	45/60	188

D 1111 C		1	1		1
Facility Component -	(Infection				
Annual Facility Survey	Preventionist)				
57.138: Laboratory-	Registered Nurse				
identified MDRO or CDI	(Infection			,	
Event for LTCF	Preventionist)	250	8	15/60	500
57.139: MDRO and CDI					
Prevention Process	Registered Nurse				
Measures Monthly	(Infection				
Monitoring for LTCF	Preventionist)	250	12	5/60	250
57.140: Urinary Tract	Registered Nurse				
Infection (UTI) for	(Infection				
LTCF	Preventionist)	250	9	30/60	1,125
57.141: Monthly	Registered Nurse				
Reporting Plan for	(Infection				
LTCF	Preventionist)	250	12	5/60	250
	Registered Nurse			•	
57.142: Denominators	(Infection				
for LTCF Locations	Preventionist)	250	12	3	9,000
57.143: Prevention	,				,
Process Measures	Registered Nurse				
Monthly Monitoring for	(Infection				
LTCF	Preventionist)	250	12	5/60	250
ПСГ	Registered Nurse	250	12	3/00	250
57.150: LTAC Annual	(Infection				
	Preventionist)	400	1	30/60	200
Survey	-	400		30/60	200
57 151 Dalada A	Registered Nurse				
57.151: Rehab Annual	(Infection	1 000		05/60	4.1.
Survey	Preventionist)	1,000	1	25/60	417
57.200: Healthcare					
Personnel Safety	Occupational				
Component Annual	Health				
Facility Survey	RN/Specialist	100	1	8	800
57.203: Healthcare	Occupational				
Personnel Safety	Health				
Monthly Reporting Plan	RN/Specialist	100	9	10/60	150
57.204: Healthcare	Occupational				
Worker Demographic	Health				
Data	RN/Specialist	100	200	20/60	6,667
	Occupational				
57.205: Exposure to	Health				
Blood/Body Fluids	RN/Specialist	100	50	1	5,000
57.206: Healthcare	Occupational				
Worker	Health				
Prophylaxis/Treatment	RN/Specialist	100	30	15/60	750
57.207: Follow-Up	Laboratory			,	
Laboratory Testing	Technician	100	50	15/60	1,250
57.210: Healthcare	100111101011	100		13/33	1,233
Worker	Occupational				
Prophylaxis/Treatment-	Health				
Influenza	RN/Specialist	600	50	10/60	5,000
TIILTUGIIZA		000	30	10/00	3,000
E7 200. Homos-i-ailar	Medical/Clinical				
57.300: Hemovigilance	Laboratory	EOO	1		1 000
Module Annual Survey	Technologist	500	1	2	1,000
57.301: Hemovigilance	Medical/Clinical				
Module Monthly	Laboratory			0/	
Reporting Plan	Technologist	500	12	2/60	200

57.302: Hemovigilance	Medical/Clinical				
Module Monthly	Laboratory				
Incident Summary	Technologist	500	12	2	12,000
57.303: Hemovigilance	Medical/Clinical				
Module Monthly	Laboratory				
Reporting Denominators	Technologist	500	12	30/60	3,000
	Medical/Clinical				
57.304: Hemovigilance	Laboratory				
Adverse Reaction	Technologist	500	120	10/60	10,000
	Medical/Clinical				
57.305: Hemovigilance	Laboratory				
Incident	Technologist	500	72	10/60	6,000
Total Est Annual Burden Hours					3,562,6
Total Est Amidal Bulden nouls					53

DATE: July 3, 2012

Kimberly S. Lane, MBA
Deputy Director
Office of Scientific Integrity
Office of the Associate Director for Science
Office of the Director
Centers for Disease Control and Prevention

[FR Doc. 2012-17987 Filed 07/25/2012 at 8:45 am; Publication Date: 07/26/2012]